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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,741	07/07/2003	Kimberly A. Anderson	S16.12-0136	6207

27367 7590 12/13/2007
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EXAMINER

GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,741

Applicant(s)

ANDERSON ET AL.

Examiner

Suba Ganesan

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-24,26,27 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,22-24,26-27,30-34,36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Status of the Claims

Claims 20,22-24,26-27,and 30-38 are currently pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 20, 22-24, 26-27 and 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross (5,089,015) in view of Williamson IV et al (6,402,780), further in view of Lane et al. (6,334,973).

2. Ross discloses a method for attaching a stentless porcine heart valve prosthesis comprising inserting fasteners (sutures) through the prosthesis through an aortic wall (col. 4, lines 16-26), the prosthesis comprising leaflets with reinforced valve commissures (Fig. 2B) Note that the examiner is considering the Dacron cover depicted in Fig. 2B to be a reinforcement covering the commissure supports, consequently the reinforcement is attached to the surface of the commissure supports. However Ross does not disclose the fastener having a head and barbed tip. Williamson IV et al teaches the use of a fastener having a head and sharp barbed tip (e.g. Fig. 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of a fastener having a head and tip, as taught by Williamson IV et al, to a method as per Ross, the fasteners of Williamson IV et al being capable of connecting vascular tissues or implants to tissues (see abstract) in situations where the use of sutures would be more difficult (col. 2, lines 5-18). It would have further been obvious to one of ordinary skill in the art to attach the fasteners to the reinforcement prior to inserting the faster in the aortic wall, root, or pulmonary artery wall for the purpose of reducing operating time by preloading the fasteners onto the implant.

3. Ross and Williamson IV appear to lack a reinforcement attached to the inner surface of the commissure support having apertures for insertion of the fastener. Lane teaches the use of an inner commissure support 10 with apertures (see figs 2-3, for example). Lane further teaches a reinforcement 24 with holes (see fig 3) attached to the outer surface of the prosthesis (noting that the inner surface is defined as the valve leaflets and immediate surrounding frame 10). The reinforcement of Lane further covers

the valve scallops and defines a curvilinear path. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include a reinforcement on the inner surface of the commissure support with holes as taught by Lane, since doing so would simply be a combination of prior art elements combinable using known methods and yielding predictable results. It would have been apparent to one of ordinary skill in the art at the time of the invention to use the fastening mechanism of Ross and Williamson IV with the commissure support reinforcement of Lane to yield a fastening mechanism that involves placing fasteners through holes in the commissure support reinforcement, the motivation being: providing a more secure attachment with a reduced risk of tearing or perforating the valve prosthesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 12/10/2007

/William H. Matthews/
Primary Examiner
AU 3774